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TITLE: Burn Patient Acuity Demographics, Scar Contractures and Rehabilitation Treatment Time Related to Patient Outcomes (ACT)

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14. ABSTRACT

The third year of the ACT proved to be a turning point for the burn rehabilitation study. During this past year, patient screening and subject enrollment with subsequent data collections began at seven participating facilities. Processes to support the ACT in terms of individual site contracts, protocol submission and training progressed forward. No major impediments were encountered. The ACT continues on course to become a most formidable research project contributing to improvement in the knowledge and understanding of how best to optimize patient outcomes in the future.

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Introduction

Burn Patient Acuity Demographics, Scar Contractures, and Rehabilitation Treatment Time Related to Patient Outcomes, conveniently referred to as the ACT representing Acuity, Contractures and Time, is a burn rehabilitation research project awarded to the American Burn Association (ABA) in September 2008 from the U. S. Army Medical Research and Materiel Command (MRMC). The purpose of the ACT is to investigate patient rehabilitation from burn injury and collect for analysis treatment information during the acute and intermediate phases of burn rehabilitation. In particular, the ACT is primarily interested in investigating the influence that time spent receiving rehabilitation treatments has on patient outcomes.

In September 2011, the ACT research study completed its third year of operation. Originally, the ACT was projected to be completed in three years but a request for an additional year was granted extending completion until October 2012. This year concludes the current three of four year ACT plan. During the first year of operation, efforts were directed on getting the ACT up and running. The second year of the ACT was spent developing the structure and framework for data collection. This past year saw the ACT transition from development into actual data collection as is further described in this report.

At the outset, the ACT had two purposes. The first was to convene a rehabilitation summit meeting which was met during the first year as previously reported. The second aim was to conduct a prospective, multi-center study of burn rehabilitation, the progress on which is elaborated upon in the remainder of the report.

Body

Aim 1

Burn Rehabilitation Summit Meeting and Publication of Proceedings – Accomplished 2009

Aim 2

Burn scar contractures are a problem for the burn survivor. Although scar contractures become apparent following would closure, the biologic process to repair and close the burn wound leading to scar contracture begins almost immediately after the burning process stops. Rehabilitation treatment delivered prior to beginning the long-term rehabilitation phase of care is paramount to successful patient outcomes. It is the interaction of these treatments provided, beginning at patient admission to the burn treatment facility up until patient discharge, coupled with time which constitutes the important data collection features of the ACT.

Organizational Structure

During the past year, the three (3) principal organizations involved in the performance of the ACT, namely the ABA, the U. S. Army Institute of Surgical Research (ISR), and the Data Coordinating Center (DCC) at the University of California-Davis (UCD), have maintained their relationships in the environment of continued ACT growth and development. The ABA has added staff members to pursue individual facility contracts and for budget oversight, the ISR, housing the lead principal investigator, has continued to progress the ACT forward, and the DCC has grown its personnel in the direction of parceling out activities such as data auditing, report outputs, and other responsibilities as further described in the logistics section.

The ACT experienced a decrease in its number of participating facilities from seventeen (17) to sixteen (16). Harborview Burn Center in Seattle WA decided to withdraw further pursuit of participation in the ACT. However, the loss of Harborview does not decrease the anticipated broad applicability of the ACT results at completion as, geographically, the northwest sector of the United States continues represented by the Oregon Burn Center. Additionally, the elimination of Harborview does not affect the number of verified burn centers (14) contributing data to the ACT as the recently added Oregon Burn Center is a verified burn center as well.

Logistics

This past third year of the ACT achieved a milestone at the outset in September 2010 with conversion of the ACT from project development to data collection. ACT data collection officially began at its first site (ISR) as it was the only site at that time ready to convert from the trial to the production platform. Concurrently, all other sites continued ACT development at various individual stages of preparedness. Throughout the year, there occurred continued ongoing and concomitant preliminary development with the various participating burn centers to varying degrees in an effort to advance them to the data collection stage. Several logistical requirements exist before actual data collection can begin at any site which preliminarily includes: 1) facility contract agreement with the ABA to the satisfaction of both entities to participate; and 2) successful ACT protocol submission and approval both locally by the individual facility Institutional Review Board (IRB) and secondarily by MRMC Human Research Protection Office (HRPO). A third necessary item is scheduled training and practice of ACT processes including subject screening and qualifications for entry into the ACT; subject enrollment into the data collection system; data collection and reporting.

To date, through the efforts of the ABA central office, fourteen (14) of the sixteen (16) participating burn centers have fully executed contracts with the ABA (Appendix A).

The remaining two (2) facilities have progressed through a negotiation phase and into a contract pending finalization and signature status.

Since last year's report, parallel effort has continued to be expended in assisting ACT facilities to meet regulatory requirements of protocol submission and approval. A year ago, only seven (7) facilities had achieved local protocol approval with only two (2) of those having received secondary HRPO approval. Presently, local protocol approval has been accomplished at 14 of the 16 facilities doubling the mark from last year (Appendix B). Moreover, there has been a five-fold increase in sites receiving secondary approval increasing the current total number to ten (10). At present, two (2) other facilities are undergoing secondary review and follow-up is in process at the remaining four (4) sites as to their status.

Formal ACT training occurred at an additional seven (7) facilities during the past year as well, bring to ten (10) the total number of sites that have undergone the one-day training session (Appendix C). One additional site is currently scheduled for training and the remaining five (5) sites will undergo the same once their previously described prerequisites are met. A push will be made to get this accomplished within the next two quarters. Seven (7) sites began screening and enrolling subjects during this past year. Activity pertinent to this advancement is discussed more fully in detail under the Key Accomplishments section.

Two untimely and unforeseen events occurred during the past year that interfered with ACT subject enrollments. The first was the sudden departure of the principal investigator from Via Christi Burn Center in Wichita KS in May. Via Christi had begun screening ACT patients in April 2011 and had enrolled two subjects at the time. According to HRPO regulations, a replacement PI must be investigated and approved before assuming this responsibility. Due to required documents for PI's, these needed to be acquired and submitted for approval. Subsequent approval for the new PI has been attained and the facility is expected to resume screening again in the next quarter.

The second unfortunate occurrence was the unexpected death of a designated PI at another facility who was on the verge of submitting their protocol documents for secondary approval. Due to this untimely event, a new PI with supporting documents as described needed to be identified. Had this misfortune not occurred, this facility probably would have been screening patients. In the interim, a new PI was recruited and the process of re-application is underway.

Following ACT training, trained individuals are given time to practice pseudo data collection and entry on imaginary subjects in the Velos *e*Research testing platform . Due to varying circumstances unique to each institution, latitude is given facilities to

complete practice training at their own pace to the point of them being comfortable to begin formal data collection. During this time, the lead PI of the ACT is available to problem solve and trouble shoot circumstances that arise. Once a facility indicates they are ready to begin screening patients for subject enrollment, each person needing access to the computer data collection systems (Velos *e*Research and Surface Area Graphic Evaluation - SAGE) completes two application forms for permission to access the production, or 'live' ACT web-based site.

One preemptive alteration to ACT training was to change from relying on verbal verification that local computers are compatible to run the Velos and SAGE computer programs to actually testing the systems beforehand. In the first few training experiences, computer program software incompatibilities were encountered on the day of training. Correction of such problems required a couple of hours in a couple of instances forcing longer than planned day-long sessions. In order to avert such situations, training computers scheduled for use are tested beforehand and problems are remedied ahead of scheduled ACT training.

Over the past two (2) years, since the inception of the ACT, the Regulatory Committee and Quality Management (RCQM) division of the U. S. Army Institute of Surgical Research (ISR) as lead site has fully supported the governance of shepherding protocol approvals through the IRB processes both at individual site locales and at HRPO. During this time, the Data Coordinating Center (DCC) at the University of California – Davis (UCD) has been in the process of gearing-up their capabilities to the point that it now has assumed full responsibility of this function. A full-time employee has been hired to oversee this responsibility at the DCC. In addition to reviewing protocol documents for completeness, the DCC is now interfacing with HRPO and monitoring for protocol continuing reviews.

From the beginning of patient screening and subject enrollment, enrollment registers have been routinely submitted to the DCC on a regular monthly basis by all sites as they have become active. Outputs of the screening logs and enrollments registers are seen in the Key Research Accomplishments section of this report. Part and parcel of routine enrollment submissions has been audit activity of the screening forms and early subject data submissions. Beginning in April 2011, representatives from the DCC and ISR began weekly teleconference meetings to review data on subjects submitted to the ACT from ISR. An audit of CRFs was preliminarily performed before each weekly teleconference. Information and data discrepancies were acknowledged, discussed and corrected when applicable. Off-track tendencies in reporting were singled out and likewise discussed. Unresolved issues were investigated during the following week and reported on at the subsequent weekly meeting. This routine was performed on the first

30 ACT subjects up to concurrence with enrollment at the time. Since then, sporadic meetings have occurred as subject records are completed.

In terms of additional site audits, the same screening process of enrollments is employed. Additionally, when a data set is completed, and prior to submitting an invoice for remuneration, the representative from ach ACT participating site is to notify the lead PI. With administrative rights to view data submission, the lead PI has been reviewing the CRF data for correctness and completeness. Issues with subject data are brought to the attention of the satellite facility representative either verbally or in written form and subsequently discussed. Any necessary corrections are made and the CRF resubmitted to the ACT. Once a validated data set is acknowledged by the lead PI, the facility is allowed to invoice for said subject(s). This process has worked well to date with few numbers of subject data being submitted by current facilities. As activity increases in this regard, the need for data screening triggers is anticipated.

An amendment was made to the ACT protocol in December 2010 to remove Harborview Medical Center as a participating ACT site. The amendment, approved by the ISR governing IRB, was circulated to all participating sites for change as well. No other amendments have become necessary since that time and a limited number of clarifications of the Case Report Forms (CRFs) have become necessary since data collection has begun. One such example is to have a 'Not Applicable' selection added to the Facial Contracture collection area on Discharge Form 1 of 3. Presently, only a "None" possibility exists for discerning between prevention or non-applicable of facial contracture. Discriminating actual versus the potential of facial contracture when a face burn is present will need considered during the time of analysis.

An Invoice template was created by the ABA for ease in delineating, tracking and submitting for remuneration of subject data (Appendix D). There are two parts. The first page is a breakout of the charges for: 1) Consenting and entering a subject into the ACT database, 2) a section for tracking the number of hospital days, 3) a section for entering in the number of range of motion measurements, 4) a section for including if lower extremity strength measurements were recorded, and finally 5) a section for a one-time reimbursement of time spent during training. The second page is a delineation of charges based on hospital days and range of motion measurements taken. Whereas the first page is an aggregate sum total of charges for all subjects' data during a given time period, the second page provides for detailed information on up to five (5) subjects per page. As indicated at the top of the Invoice, timely submissions of invoices are due by the 5th of each month. This deadline is such so that the ABA can submit to MRMC by the 10th of each month for processing and distribution of ACT funds back to the ABA for disbursement to the ACT participating sites.

Adverse Events and Protocol Deviations

No adverse event nor protocol deviation have been reported since implementation of data collection began.

Data Coordination Center (DCC) Website

During the last year, the DCC developed a website and home page for their burn research activities (Appendix E). The web address is: http://ucdavisdcc.org/default.aspx. As can be seen on the homepage (red rectangle), the ACT is listed as one of several burn research projects with which the DCC is assisting in statistical analysis and data collection. On this site, ACT facilities can access documents such as the latest version of the protocol and the Standard Operating Procedures (SOP) Manual. Also, when the time comes for facility individuals to apply for access rights to the ACT production side of Velos as previous described, they can down load the permission forms from this site. This availability eliminates the need for the lead PI to have to send to the DCC a list of names with contact information for the DCC to send out the forms and have them returned. In the future, 'on-line' meetings will be possible as well as instant messaging.

Development Meetings/ Documentation/Communication

In February 2011, the Multi-Center Trials Group of the ABA, an advisory body to the Association on research-related activities, hosted a meeting in Washington DC in conjunction with their annual National Leadership Meeting. As part of the agenda for the meeting, all primary investigators of ABA sponsored research activities were invited to attend and present an update on the status of each respective research protocol.

At the annual meeting of the ABA in March 2011 held in Chicago, an ACT Investigators Meeting (IM) was held. The purpose of the IM was to update ACT facility representatives as to study status and changes and to discuss any issues pertinent to the study or individual facilities. Twenty-six (26) representatives from 14 of 16 ACT participating sites were in attendance including members from the ABA and the DCC. The University of Iowa and St Joseph Burn Center were not represented but received follow-up information.

Over the past year, all required quarterly reports were completed and submitted on time. Miscellaneous requests from other individuals central to the ACT for additional reports or other activities were honored. Communication between ISR and HRPO, as well as the DCC, over protocol submission and approval was performed in an expedient manner. Throughout the year, numerous emails and communication by telephone

between all entities involved in the ACT including and within the ABA, DCC, SAGE, ISR, HRPO, and facility representatives were exchanged.

Budget

The ACT continues substantially under budget overall having expended 33.75% of its approved funding (Appendix F). The largest underutilized portion of the budget appropriations has been in the area of facility site remuneration for data collection. To date, only 5.9% of the budget has been expended in this regard. However, with the ACT having moved into data collection per this report, a much larger expenditure of funds from this line item is anticipated over the ensuing year.

Per the previously established CRADA between the ABA and ISR, the first round of yearly funds for statistician support was paid. In addition, the ISR has subsequently invoiced for the second year of statistical support, consistent with the terms of the CRADA. Per the Research Directorate at ISR, those funds include ISR directs and indirects; with those indirects split out once the funds arrive at ISR. Consistent with policy, the ABA takes no overhead/indirects on these incurred expenses.

Lastly, minor budget adjustments have been made to accommodate for the considerable outside legal fees associated with contract negotiations with over 16 different institutions and their counsels; ABA Study Coordinator Time and ABA Travel have been decreased accordingly.

Key Research Accomplishments

The major accomplishment for the ACT was transitioning from project development and testing into production and actual subject data collection. Enrollment of subjects into the ACT has mirrored the conversion of participating sites from preparatory and preliminary requirements as previously noted to crossing over into real time subject enrollment.

Screening first began at the ISR on 26 September 2010 with the first subject being enrolled at that site on 5 October 2010. After that time, six (6) additional sites began screening for subjects and have entered subjects into the ACT per Appendix G. As of this report, 745 patients total have been screened to date at the seven (7) currently enrolling sites accounting for 56 actual enrollments. As previously reported, the ACT is powered to require 435 subjects total be entered into the ACT. The current enrollment of 56 subjects represents 12.9% of the total expected enrollments.

Of the total number of patients screened (745), Appendix H provides a breakdown as to screening number related to enrollment fallout. Of the total number of potential

patients screened for ACT entry, the vast majority (73.3%) did not meet the eligibility criteria for admission into the ACT. Eligibility criteria for the ACT were established at such a level to by-pass what was thought to be patients who would not have contributed substantially to the aim of the ACT itself.

However, almost one (1) out of every five (5) patients, (20%) admitted to participating burn centers do not make it into the ACT. The main reason (51.4%) is due to therapist capacity. As described previously, therapist capacity is a self-imposed limitation of individual burn center to accept subjects into the ACT based on various factors including burn rehabilitation staff size and research support provided by each institution. The number of subjects each burn center accepts is decided upon by each individual site. Once the site-specific predetermined number of subjects are enrolled into the ACT, then the next potential enroll can be by-passed because of therapist capacity to only have one subject at a time. Once a subject is discharge from the hospital, the next available subject must be enrolled based on the ACT 'rolling enrollment' procedure. Unable to consent a patient ranks second as to why patients fail to make it into the ACT study while only 13% of patients have outright declined participation in the ACT.

Subject enrollment into the ACT has been steady (Appendix I) and partially reflects the number of patient screenings performed except for the limiting factors as described in the previous paragraph. Screenings in the fourth quarter rose substantially and were almost equal to all of the first three quarters combined. The reason for the dramatic rise in screenings is due to the addition of two large and active burn centers coming on board in the last quarter to begin screening as noted in Appendix G. During this time, Loyola University and New York Presbyterian burn centers added 200 patients to the screening roster.

A demographic breakdown and comparison of patient screenings and subject enrollments can be seen in Appendix J. It is interesting to note the percentage similarities between those patients screened and those subjects ultimately enrolled for all categories of gender, ethnicity and race.

One of the earliest professed and described strengths of the ACT was the widely represented geographic distribution of the burn centers participating in the ACT. The fact that these demographics are so closely aligned is encouraging as to the potential broad application of the final results of the ACT to the practice of burn rehabilitation in the United States.

In terms of overall enrollments relative to percent burn categories (Appendix K), several interesting findings appear. First is that of the estimated highest anticipated

enrollment category of burns in the 2 – 10 percent range is the lowest category by percentage. Similarly and proportionately, mid-sized burns have been enrolled to the greatest degree. This tendency, if continued, would lend additional substantive meaningful information for burn rehabilitation as described below.

Previously, burn scar contracture appearance has been associated with percent total body burn and depth of burn. Being able to collect data on patient outcomes from those experiencing larger size burns would add greatly to the burn rehabilitation body of knowledge. Regardless of poor or favorable patient outcome, patient with greater extent body burns have always been most problematic to treat. So having more information to analyze as to eventual outcome would be highly beneficial to the end points of the ACT if this trend continued.

Lastly, it is also interesting that the largest burn size with data collected is in the 51 – 60 percent category and actually is a 51 percent burn. As in the previous paragraph, it would be desirable to be able to collect and analyze a larger data set of subjects with more extensive burns. However, with an exclusion criterion of "non-survivable injury," it remains to be seen how many subjects actually get enrolled into the ACT with more extensive or life threatening burns.

Reportable Outcomes

1) Based on one participating site's existence in the ACT to date (ISR), there was sufficient information available to support writing and submitting an abstract for consideration to present at the 2012 annual meeting of the ABA. The information centered on burn splint prescription and patient wearing times as collected from the Velos CRF Daily 2 of 2 which tracks splint wear time and frequency.

2) With the number of centers contributing data during the past year, the level of activity is encouraging as to overall subject enrollment expectations as it only represents just under one-half of all potential sites. However, projecting out this number of enrollments onto all 16 sites, this would equate to approximately 66 subject enrollments per quarter which would fall short of meeting the 435 total enrollments needed for the ACT within the next four (4) quarters, or last approved year for the ACT. Based on this projection, it is estimated that nearly six (6) additional quarters will be needed to collect data on the required number of subjects. With this estimation another no cost extension will be pursued.

Conclusion

Half-way into the approved study time for the ACT, the research project effort has turned a major corner moving into a data collection phase. This process is gaining

traction in terms of both facility participation and subject enrollment. Arguably, overall progress of the ACT has been slower than anticipated but not without substantiated reasons. As previously indicated, the fact that there has been a protracted ramp-up time for the ACT has allowed incremental system implementation which has permitted the ACT to begin on a solid foundation.

Nevertheless, forward progress has been made with an anticipated trajectory towards the majority of data collection being performed during the ensuing year. Within this framework, additional effort needs to occur in the area of data management and preparation for analysis. Most importantly, the ACT overall continues on course to creating a viable and worthwhile contribution to the understanding of burn rehabilitation processes and improving patient outcomes.

Appendices

Appendix A

ABA-Burn Center Contract Status

Fully Executed

1. Arizona Burn Center
2. Regions Hospital
3. University of Utah
4. St Joseph's Medical Center
5. Loyola Medical Center
6. USAISR (CRADA)
7. Via Christi
8. University of California Irvine
9. New York Presbyterian
10. University of North Carolina
11. Legacy Emanuel
12. St Elizabeth Medical Center
13. University of California Davis
14. University of Texas Houston

Pending

1. University of Iowa
2. Inland County Arrowhead

Appendix B

ACT Facility IRB Status

Facility Name	Local Approval	Secondary Approval
U. S. Army Institute of Surgical Research	✓	✓
University of California Davis	✓	✓
St. Elizabeth Regional Medical Center	✓	✓
Via Christi Regional Burn Center	✓	✓
St Joseph Burn Center	✓	✓
Arizona Burn Center	✓	
University of California Irvine	✓	
New York Presbyterian Hospital	✓	✓
Oregon Burn Center	✓	✓
North Carolina Jaycee Burn Center	✓	✓
Loyola University Medical Center	✓	✓
University of Utah	✓	✓
Regions Hospital	✓	
University of Iowa	✓	
Hermann Memorial Hospital		
Inland Counties Hirschman Burn Center		

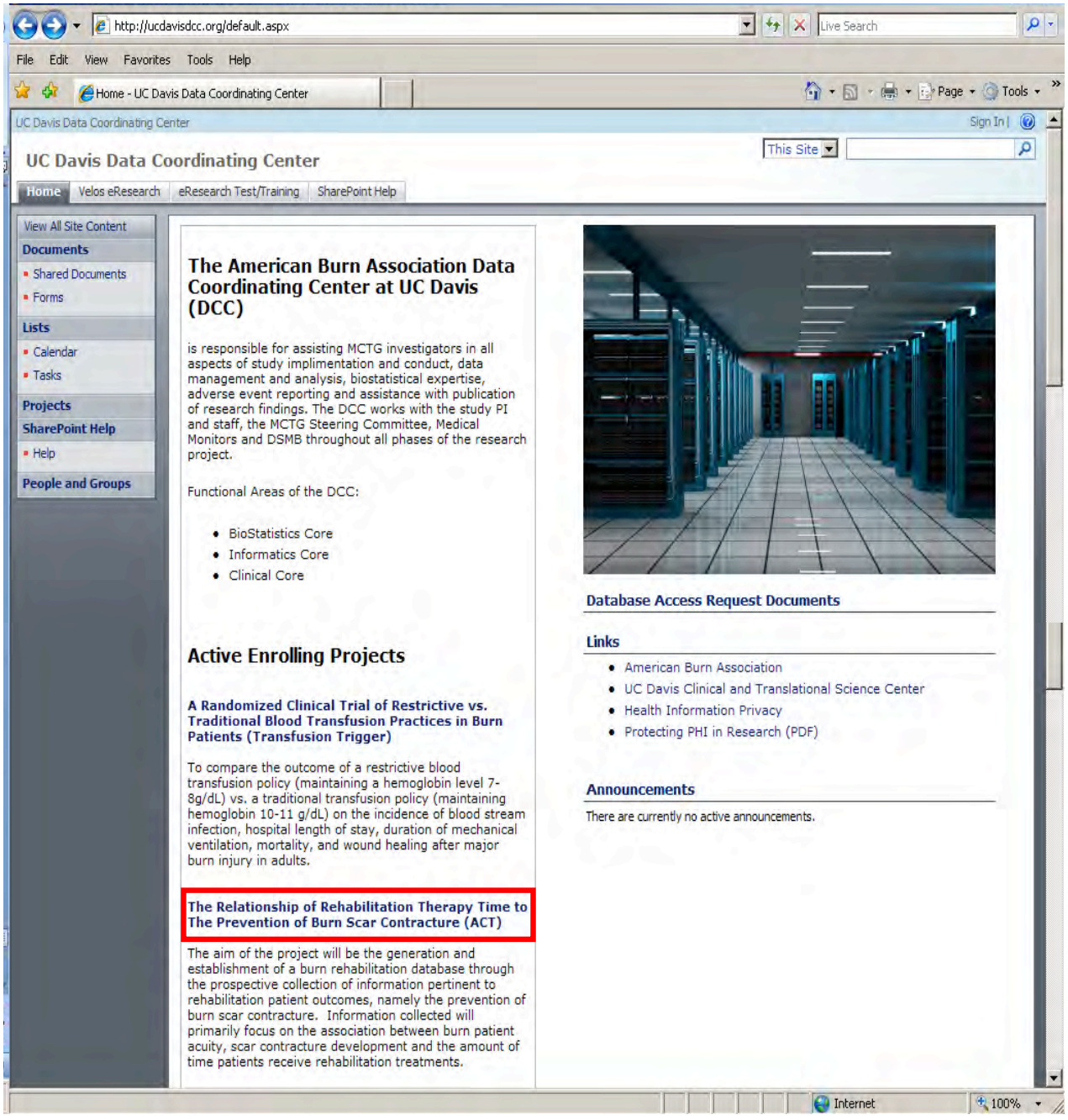
Appendix C

Site Training Calendar

Facility	Date Trained
1. Institute of Surgical Research	May 2010
2. University of California – Davis	June 2010
3. St Elizabeth's Medical Center	September 2010
4. Via Christi Medical Center	October 2010
5. Legacy Emmanuel Burn Center	December 2010
6. Loyola Medical Center	February 2011
7. New York Presbyterian	May 2011
8. St Joseph	August 2011
9. University of North Carolina	August 2011
10. University of Utah	August 2011

Appendix E

Data Coordinating Center Home Page



Appendix G

ACT Site Subject Enrollment

Facility Name	Began Screening	First Enrollment
U. S. Army Institute of Surgical Research	9/26/2010	10/5/2010
Via Christi Regional Burn Center	4/7/2011	4/27/2011
Loyola University Medical Center	6/2/2011	6/20/2011
St. Elizabeth Regional Medical Center	6/7/2011	6/20/2011
New York Presbyterian Hospital	8/152011	8/17/2011
Oregon Burn Center	8/15/2011	9/3/2011
University of California – Davis	8/25/2011	8/31/2011

Appendix H

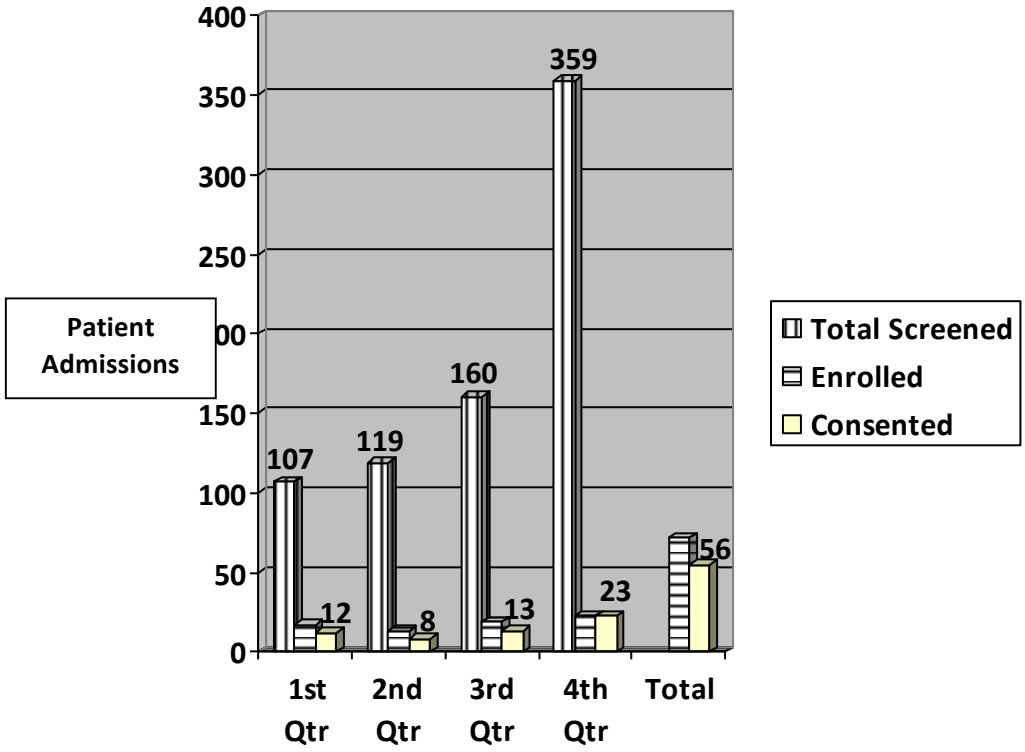
ACT Patient Screening Outcomes

Total Subjects Screened	745	
Eligible and Consented	56	7.5%
Not Eligible	546	73.3%
Eligible but Not Consented	138	18.5%

Reason Not Consented		
Unable to Consent/No Family	38	27.5%
Declined	18	13.0%
Therapist Capacity	71	51.4%
Other	11	7.9%

Appendix I

Subject Enrollment



Appendix J

Demographic Distribution

	Screened	%	Enrolled	%
Gender				
Male	569	76.4	43	76.8
Female	176	23.6	13	23.2
Ethnicity				
Hispanic	239	32.1	13	23.2
Non-Hispanic	472	63.3	38	67.9
Unknown	34	4.5	5	8.9
Race				
African American	72	9.7	6	10.7
American Indian/Alaska Native	1	<1	0	0
Asian	15	2.0	1	1.8
Caucasian	576	77.3	43	76.8
Native Hawaiian/Pacific Islander	1	<1	0	0
Not Reported	31	4.2	3	5.4
Unknown	49	6.6	3	5.4

Appendix K

Subject Enrollment per % Decile Burn Injury

Burn Percent Category	Estimated Number of Enrollments	Actual Number of Enrollments to Date	Percent (%) Accrual
2-10	292	25	8.6
11-20	82	15	18.3
21-30	27	11	40.7
31-40	13	3	23.1
41-50	7	1	14.3
51-60	5	1	20.0
61-70	4		
71-80	3		
81-90	1		
90-100	1		